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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,243	10/15/2001	Juan-Carlos Diaz	P842 CIP	4113

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MEDTRONIC VASCULAR, INC.
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EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,243

Applicant(s)

DIAZ, JUAN-CARLOS

Examiner

Michael Thaler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☒ Claim(s) 2-10, 12-22 and 25-27 is/are allowed.
6) ☒ Claim(s) 1, 11, 23, 24 and 28-32 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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The disclosure is objected to because of the following informalities: In claim 5, line 3, "is" should be inserted after "thickness". Claims 15 and 31 should be also amended in this way. A period should be inserted at the end of claim 24. Appropriate correction is required.

Claims 1, 11, 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiedler (5,817,101) in view of Luckic et al. (5,709,703). Fiedler, in figures 1-3, discloses catheter 22 having a guidewire lumen 24 and pressurizing lumen 26, fixed seal mount (the portion of catheter 22 which supports seal 38), sheath 36 having a movable seal mount (the portion of sheath 36 which supports seal 40), a stent retention portion of said sheath (the portion of sheath 36 which surrounds stent 50 prior to stent deployment), a stent retraction portion of said sheath (the proximal portion of sheath 36 which surrounds seal 38 prior to stent deployment), first seal structure 38 and second seal structure 40. Fiedler fails to disclose the stent retraction portion of the sheath as having an inner surface made of a material different from the material of an inner surface of the stent retention portion of the sheath. However, Luckic et al. teach that a stent containment sheath 2 should include several sections, including a scratch protection tube 18 at the distal end of the sheath in order to obtain the advantage of preventing

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the stent from scratching the sheath (col. 2, lines 13-60 and col. 7, lines 9-24). It would have been obvious to include a scratch protection tube in the distal end of the Fiedler sheath 36 so that it too would have this advantage. With this modification, the stent retention portion of the Fiedler sheath 36 would be made of a first material (the metal of Luckic et al. ring 18 incorporated into the Fiedler sheath 36) having a lubricious surface quality while the stent retraction portion of the Fiedler sheath 36 would have a smooth inner surface of a second material (the polymeric material of the main portion of sheath 36 noting col. 7, lines 1-9 of Fiedler) different from the first material. Further, the inner surface of the Fiedler stent retention portion of the sheath 36 (including the Luckic et al. ring 18 incorporated therein) would be exposed to the stent containment sheath lumen as now claimed. Fiedler fails to disclose a "stent plunger" to provide a backing for the stent. However, Luckic et al. teach that a stent should be supported or backed by a rigid stop 37, 41 apparently in order to prevent it from migrating proximally within the sheath during sheath retraction as well as providing the advantage of preventing the stent from scratching the catheter (col. 7, line 61 to col. 8, line 16). It would have been obvious to include a rigid stop on

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the Fiedler catheter 22, separate from flexible seal 38, so that it too would have this advantage.

Claims 28-32 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Randall et al. (6,514,261). Randall et al. disclose a catheter having a guidewire lumen (col. 3, line 49), a stent retention section which extends (proximally) from a stent plunger 28 and a sheath retraction section (the portion of tube 14 which extends distally from plunger 28), stent containment sheath 10 and spacer 12 which is loosely contained within the stent containment sheath 10 and outside the sheath retraction section (since the sheath 10 can slide relative to spacer 12). Spacer 12 is inherently sized to substantially interfere with the kinking of the stent containment sheath when the stent containment sheath containing a portion of the catheter is bent since any kinking that sheath 10 experiences will be limited due to its contact with spacer 12 as the sheath is bent. Alternatively, it would have been obvious that spacer 12 is sized to substantially interfere with the kinking of the sheath for this reason. As to claim 30, spring 12 has a substantially planar coil shape since each winding of the coil lies substantially within a plane because each winding contacts the adjacent winding since the spring is fully compressed as

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indicated in col. 4, lines 40-43 and as shown in figure 1. As to claim 31, the thickness of the spring 12 tapers to a smaller thickness near its outer edge due to the round cross-section of the wire of the spring. As to claim 32, the windings of spring 12 are "stacked" rings since they abut one another along the length of the spring.

Claims 2-10, 12-22 and 25-27 are allowed.

Applicant's arguments with respect to claims 1, 11, 23, 24 and 28-32 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated


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from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (571)272-4704. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

mht
5/17/05



MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3731